

JUSTIFICATION
FOR AN EXCEPTION TO FAIR OPPORTUNITY

1. Contracting Activity: Department of Veterans Affairs (VA)
Office of Acquisition Operations
Technology Acquisition Center
23 Christopher Way
Eatontown, NJ 07724
2. Description of Action: This proposed action is for a Firm-Fixed-Price Delivery Order to be issued under the National Aeronautics and Space Administration (NASA) Solutions for Enterprise-Wide Procurement (SEWP) V Government Wide Acquisition Contract (GWAC) for Micro Focus SUSE Linux software licenses and maintenance subscriptions.
3. Description of the Supplies or Services: VA, Office of Information and Technology, Service Delivery and Engineering, Field Operations National office has a requirement for the renewal of 357 brand name Micro Focus SUSE Linux software licenses and maintenance subscriptions that are installed throughout VA. This license and subscription renewal supported currently fielded Enterprise SUSE Linux Operating Systems (OS) supporting the Veterans Health Information System Technology Architecture (VistA) Imaging Platform, which enables VA to continue automatically distributing and installing tested and approved Linux OS releases and configuration items, assuring reliable standardized system operations, and effective system security for VistA. The SUSE brand name products also allow VA to monitor the performance of the current VistA Imaging Platform computers controlled by the Enterprise Linux OS, helping to ensure reliable operation. This allows VA to satisfy ongoing maintenance, security, and operational requirements for existing development, test, validation, and production applications and systems executing on SUSE-Linux-controlled computers. The license and subscription renewal grants VA access to the required software releases, updates, technical support, and provides training to ensure continued seamless operation of the VistA Imaging environment without any required downtime.
4. Statutory Authority: The statutory authority permitting an exception to fair opportunity is Section 41 U.S.C. 4106(c)(2) as implemented by the Federal Acquisition Regulation (FAR) Subpart 16.505(b)(2)(i)(B), entitled "Only one awardee is capable of providing the supplies or services required at the level of quality required because the supplies or services ordered are unique or highly specialized."
5. Rationale Supporting Use of Authority Cited Above: Based on market research, as described in section 8 of this justification, it was determined that limited competition is available among authorized resellers of the required Micro Focus SUSE Linux software licenses and maintenance subscriptions. The VistA Imaging System is the Picture Archiving and Communication System (PACS) for VA. It provides technologies for acquiring, storing, retrieving, and displaying images for all medical specialties within VA and for sharing artifacts and images with the Department of Defense. The Vista Imaging System stores approximately 30 petabytes of data and utilizes Micro Focus's SUSE Linux Operating System (OS) to perform these functions. Every single medical

image in VA is processed by the VistA Imaging System operating on the Micro Fuse SUSE Linux OS. No other brand name software can meet all of VA's needs. Specifically if VA were to compete a requirement for a new VistA Imaging solution that utilizes different software, the Government estimates that it would take between one to two years for another software provider to develop a required medical device solution that meets all VA functional requirements that VistA Imaging System is currently providing. Additionally, this solution would have to be tested and determined to be interoperable and compatible with the existing system and VA Infrastructure. Even if these requirements could be met, the Original Software Developer of this solution would then have to submit a new 510(k) submission in order to receive the required certification as a medical device. The VistA Imaging System is a Class 1 Medical Device, and is certified to the Food and Drug Administration (FDA) Regulation 510(k) safety and effectiveness requirements. The Micro Fuse SUSE Linux OS, as an integral component of this medical device configuration and thus, cannot be changed or modified without violating its existing FDA Medical Device certification. Specifically under Title 21 Code of Federal Regulation (CFR) 807.81 Subpart E, Paragraph (a)(3)(i), the law states "A change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process". Any modification or use of alternate software would be considered a major change of this medical device, and require submission of a new 510(k) package for review by FDA in accordance with Title 21 CFR 807.81 Subpart E Paragraph (a). Additionally, during this process, FDA would determine whether the VistA Imaging System would change its Class 1 classification for a higher classification, and therefore have additional regulatory requirements placed against it. As discussed in Title 21 CFR 807.81 Subpart E Paragraph (a), this submission is required at least 90 days before proposing to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use. FDA requires at least 90 to 180 days to process this 510(k) submission, to provide the required medical device certification. During this time, VA would have an out of date medical device, vulnerable to defect and failure. Without VistA Imaging System's continued operation it would present unacceptable risk to patient safety as this system carries every medical image processed by VA utilized in providing patient care. Therefore, the only way the required brand name license and subscription renewal can fulfill the Government's requirements and provide for sustained operation of the VistA Imaging System. Additionally, VA requires the aforementioned software maintenance subscription for the renewed SUSE Linux software licenses. Without the proper software releases, updates, and technical support the performance of the software could be degraded, ultimately jeopardizing the ability to store and process medical images. Since this software operates on a Class 1 Medical Device, any updates or changes to the software must be provided by Micro Focus as the original software developer or its authorized resellers in order for it to remain compliant with the existing FDA certification.

6. Efforts to Obtain Competition: Currently, no other software OS can provide the required functionality. Further market research was conducted, details of which are in paragraph 8 of this document. It was determined that limited competition is viable among authorized resellers for the required brand name software license and

maintenance subscription renewal. In accordance with FAR 5.301 and 16.505(b)(2), this action will be synopsisized at award on the Federal Business Opportunities Page (FBO) and the justification will be made publicly available.

7. Actions to Increase Competition: The Government will continue to review and revalidate its requirements as VistA continues to evolve. Since this requirement is classified as a medical device and therefore subject additional statutory requirements, the requiring activity will continue to monitor whether alternate devices can meet VA's needs and have the requisite FDA certification which is in accordance with Title 21 Code of Federal Regulation 807.81.

8. Market Research: Market Research was conducted in November 2015 for similar software. Specifically, VA technical experts reviewed similar software products from Microsoft Corporation and Red Hat Linux. While these products could meet some of VA's requirements, they could not meet all of VA's requirements as outlined in section 5 of this justification. Further market research was conducted in November 2015 through issuance of a Request for Information under NASA SEWP V GWAC website. It was determined that there are at least five authorized resellers of the required Micro Focus SUSE Linux software license and maintenance subscription renewal. Therefore limited competition is anticipated.

9. Other Facts: None.